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December 24, 2019

Honorable Freda L. Wolfson, Chief Judge
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Re: *In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation* (MDL No. 2738)

Dear Chief Judge Wolfson:

The PSC writes to bring to the Court's attention four peer-reviewed publications that have been published since the *Daubert* hearing and that support the PSC's general causation experts' opinions that Johnson & Johnson's talcum powder products can cause ovarian cancer:

- Steffen, JE., et al. *Serous Ovarian Cancer Caused by Exposure to Asbestos in Cosmetic Talc Powders – A Case Series Serous Ovarian Cancer Caused by Asbestos in Cosmetic Talc.* Journal of Occupational and Environmental Medicine. DOI: 10.1097/JOM.0000000000001800. (published ahead of print) (Dec. 23, 2019) (attached as Exhibit A). Investigators, including PSC experts Drs. Longo and Rigler, reported on 10 cases of serous ovarian cancer among users of Johnson & Johnson's asbestos-containing talcum powder products. They performed an asbestos exposure assessment during talc application. The investigators analyzed the surgical tissue of the patients as well as the talc containers used by the patients. Platy talc was found in the tissue of 9 out of 10 cases; fibrous talc was found in 8/10 cases; tremolite and/or anthophyllite asbestos was found in 8/10 cases. The asbestos fibers found in the cosmetic talc containers matched those found in tissues. The estimated inhaled asbestos dose ranged from 0.38 to 5.18 fiber years. None of the cases reported in the series had any known history of alternative asbestos exposure. The study provides evidence that the inhaled asbestos/fibrous talc from the application

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of cosmetic talc can cause ovarian cancer. “The unique combination of the types of asbestosiform minerals detected in cancerous tissue and ‘cosmetic’ talc is a fingerprint for exposure to asbestos-containing talc.”

- O’Brien, KM, et al. *Genital Powder Use and Risk of Ovarian Cancer: A pooled analysis*. ASPO Abstracts (American Society of Preventive Oncology). Dec. 17, 2019 (attached as Exhibit B): One of the Johnson & Johnson Defendants’ primary arguments in support of their position that the epidemiologic literature does not support causation is that the cohort studies do not show a statistically significant increased risk between genital powder use and ovarian cancer, and therefore, are inconsistent with other study designs. The National Cancer Institute’s Ovarian Cancer Cohort Consortium conducted a pooled data study from the four large cohort studies. The data included 2,073 cases of ovarian cancer. The investigators observed that there is a statistically significant 9% increase in ovarian cancer with ever powder use, compared to never use (hazard ratio [HR] = 1.09, 95% confidence interval [CI] = 1.00, 1.20). “The strongest association was observed among women with patent reproductive system, e.g. had a uterus and had not had tubal ligation, at the time powder exposure was assessed (HR=1.15, 95% CI: 1.03, 1.29). There were no clear differences by ovarian cancer subtype.” The 11 investigators who conducted the study are from institutions such as the NCI, Harvard Medical School, Johns Hopkins University, among others, and their work was funded by the NCI.
- Mandarino, A., et al. *The effect of talc particles on phagocytes in co-culture with ovarian cells*. Environmental Research 180 (2020) 108676 (attached as Exhibit C): The investigators in an *in vitro* study evaluated the immunotoxic effect of talc as compared to a control. Using macrophage cells, similar to those used by Dr. Saed, the investigators “found that murine ovarian surface epithelial cells (MOSEC), a prototype of certain forms of ovarian cancer, were present in larger numbers after co-culture with macrophages treated to a combination of talc and estradiol than to either agent alone or vehicle. Control particles did not have this effect. Co-exposure of macrophages to talc and estradiol led to increased production of reactive oxygen species and changes in expression of macrophage genes pertinent in cancer development and immunosurveillance.” These results, from independent scientists from Harvard University, the University of Rochester, and Brown University, are consistent with and support Dr. Saed’s research and opinions regarding the biological effects of Johnson’s Baby Powder in cell cultures.

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- McDonald, SA., et al. *Migration of Talc from the Perineum to Multiple Pelvic Organ Sites: Five Case Studies With Correlative Light and Scanning Electron Microscopy*. Am J Clin Pathol 2019;XX:1–18 (attached as Exhibit D). The investigators reported data from five patients with documented perineal talcum powder use. In each instance involving exposed patients, talc (talc particles and in some instances, talc fibers (i.e., fibrous talc)) was documented by polarized light microscopy and scanning electron microscopy in multiple pelvic sites distant from the perineum. These sites included pelvic region lymph nodes, cervix, uterine corpus, fallopian tubes and ovaries. The existence of morphologically demonstrated talc in multiple pelvic organ sites, including pelvic tissues and lymph nodes simultaneously, reported in this publication has not been reported in the literature previously and confirms the “biologic potential of talc, its inflammatory potential, and its migration via pelvic lymphatics from the perineum.” This publication supports the opinions of each of the PSC’s general causation experts that talcum powder can migrate from the perineum to the upper genital tract.

Thank you for your consideration of these additional scientific publications. Should the Court have any questions or require additional information, please let us know. We hope you have a happy holiday.

Very truly yours,

/s/ *Michelle A. Parfitt*
Michelle A. Parfitt

/s/ *P. Leigh O'Dell*
P. Leigh O'Dell

cc: All counsel of record via ECF notification